

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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| E8 PHARMACEUTICALS LLC and |) | |
| MASSACHUSETTS INSTITUTE OF |) | Civil Action No. 08-11132-GAO |
| TECHNOLOGY, |) | |
| Plaintiffs, |) | |
| |) | |
| v. |) | |
| |) | |
| AFFYMETRIX, INC., |) | |
| |) | |
| Defendant. |) | |

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| E8 PHARMACEUTICALS LLC and |) | |
| MASSACHUSETTS INSTITUTE OF |) | Civil Action No. 09-10832-GAO |
| TECHNOLOGY, |) | |
| Plaintiffs, |) | <u>CONSOLIDATED</u> |
| |) | |
| v. |) | |
| |) | |
| NAVIGENICS, INC., |) | |
| |) | |
| Defendant. |) | |

OPINION AND ORDER
January 13, 2010

O'TOOLE, D.J.

I. Background

The Massachusetts Institute of Technology (“MIT”) is the assignee of U.S. Patent No. 6,703,228 (the “’228 patent”), entitled “Methods and Products Related to Genotyping and DNA Analysis.” The ’228 patent claims methods, developed by Dr. David Housman and others, the practice of which permits genetic analysis, or genotyping, using small amounts of sample DNA and a small number of reactants.

On June 24, 2008, MIT entered into an “Exclusive Patent License Agreement” (the “License Agreement”) with E8 Pharmaceuticals LLC (“E8”). The License Agreement transferred

to E8, among other rights and obligations, the right to sue infringers. E8 and MIT filed suit against the defendant, Affymetrix, Inc. (“Affymetrix”), alleging that its GeneChip® products infringe the ’228 patent and further that Affymetrix actively induced infringement by directing customers to use its products according to the patented methods. A similar, and now consolidated, action was filed against the defendant, Navigenics, Inc. (“Navigenics”), which purchased assets, including the alleged infringing products, from Affymetrix in February 2009.

Pursuant to Federal Rule of Civil Procedure 12(b)(1), the defendants have moved to dismiss E8’s claims on the ground that E8 lacks standing to sue for infringement of the ’228 patent.

II. Standing

The standing inquiry is the same in patent infringement cases as in other cases. See Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc., 248 F.3d 1333, 1346 (Fed. Cir. 2001). Standing, as always, involves both constitutional requirements and prudential concerns. Media Techs. Licensing, LLC v. Upper Deck Co., 334 F.3d 1336, 1369 (Fed. Cir. 2003). Only the former are at issue in this case.¹ Constitutional standing exists if the plaintiff suffered an injury-in-fact that is both traceable to the defendant’s conduct and redressable by a favorable judicial decision. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992). The present dispute concerns only the injury-in-fact element of constitutional standing.

Injury-in-fact is the “invasion of a legally protected interest.” Intellectual Prop. Dev., Inc., 248 F.3d at 1346 (quoting Lujan, 504 U.S. at 560). In an infringement action, a plaintiff’s injury-in-fact arises from the alleged infringer’s invasion of the patent holder’s statutorily created

¹ Because MIT is a co-plaintiff in this action, prudential standing is not an issue. See Intellectual Prop. Dev., Inc., 248 F.3d at 1348 (“As a general rule, . . . this court adheres to the [prudential] principle that a patent owner should be joined, either voluntarily or involuntarily, in any patent infringement suit brought by an exclusive licensee having fewer than all substantial patent rights.”).

right to exclude others from making, using, or selling the patented invention. See 35 U.S.C. § 154(a)(1); Intellectual Prop. Dev., Inc., 248 F.3d at 1346. Put another way, the party holding the exclusionary rights to a patent suffers constitutional injury-in-fact when another makes, uses, or sells the patented invention without his consent. See Morrow v. Microsoft Corp., 499 F.3d 1332, 1339 (Fed. Cir. 2007) (“Constitutional injury in fact occurs when a party performs at least one prohibited action with respect to the patented invention that violates these exclusionary rights.”).

When a patent infringement action is brought by a licensee (as opposed to a patentee), the standing inquiry asks whether the licensee “has a sufficient ownership interest in a patent” to be entitled to sue for infringement. Propat Int’l Corp. v. Rpost, Inc., 473 F.3d 1187, 1188 (Fed. Cir. 2007); see Ortho Pharm. Corp. v. Genetics Inst., Inc., 52 F.3d 1026, 1034 (Fed. Cir. 1995) (“The key question for determining standing of a licensee is whether the licensee . . . has an exclusive property interest in the patent itself”) (internal quotation omitted). Or put another way, the question is whether the licensee holds sufficient exclusionary rights to the patent to be entitled to sue for infringement. Morrow, 499 F.3d at 1341. The right to exclude is “in effect, a bundle of rights which may be divided and assigned, or retained in whole or part.” Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA, 944 F.2d 870, 875 (Fed. Cir. 1991). This “bundle of rights” includes not only the right to sue for infringement, but also the right to indulge infringement via assignments, licenses, and sublicenses. See Propat Int’l Corp., 473 F.3d at 1194; Prima Tek II, L.L.C. v. A-Roo Co., 222 F.3d 1372, 1379 (Fed. Cir. 2000).

Licensees fall into three categories based on the share of this bundle of rights held: (1) those licensees holding “all substantial rights under the patent,” or the entire bundle of rights (“exclusive licensees of all substantial rights”), Speedplay, Inc. v. Bebop, Inc., 211 F.3d 1245, 1250 (Fed. Cir. 2000); (2) those licensees holding exclusionary rights, but not all substantial

rights to the patent (“exclusive licensees of fewer than all substantial rights”), Abbott Labs. v. Diamedix Corp., 47 F.3d 1128, 1133 (Fed. Cir. 1995); and (3) those licensees holding less than all substantial rights and lacking exclusionary rights to the patent (“bare licensees”), Propat Int’l Corp., 473 F.3d at 1194; see also Morrow, 499 F.3d at 1339-40 (describing these categories in detail).²

Here, the crucial question is whether E8 is, as it argues, an exclusive licensee of fewer than all substantial rights or, as Affymetrix and Navigenics argue, a bare licensee. An exclusive licensee of fewer than all substantial rights has standing to sue so long as the patentee is joined in the suit, whereas a bare licensee cannot participate in a patent infringement action. See Morrow, 499 F.3d at 1339-41. There is no litmus test to determine what type of licensee a plaintiff may be. Rather, to make such a decision, courts seek to ascertain the intent of the parties from the substance of what was granted by the license agreement. See Mentor H/S Inc. v. Med. Device Alliance Inc., 240 F.3d 1016, 1017 (Fed. Cir. 2001). It is helpful to consider not only the rights transferred to the licensee, but also any rights retained by the patentee. Vaupel Textilmaschinen KG, 944 F.2d at 875.

A. Right to Practice the ’228 Patent

At oral argument, counsel for Affymetrix suggested that the Court could avoid an involved standing inquiry because the *sine qua non* of patent standing is the right to practice the patent. (See Hr’g Tr. 15, Apr. 29, 2009) (“I do not think [E8] could win without the rights [sic] to practice.”). And here, the License Agreement does not include an explicit grant of the right to practice the ’228 patent.

² “All substantial rights” is a category that includes not only exclusionary rights but also legal ownership of the patent, responsibility for maintenance of the patent, and economic interests in the patent. See Propat Int’l Corp., 473 F.3d at 1189-94.

The Federal Circuit has not articulated such a bright-line rule for patent standing. However, the Supreme Court’s decision in Crown Die & Tool Co. v. Nye Tool & Machine Works, 261 U.S. 24 (1923), gives support to the defendants’ position. In that case, the Court explained that patentees hold two rights: (1) a common law right to make, use, and sell the invention which arises from the act of invention; and (2) a statutory right to exclude others from making, using, and selling the invention which arises from the Patent Act. See id. at 34. Because the plaintiff in Crown Die, a licensee,³ held only the right to exclude, the Court concluded that the plaintiff lacked standing to sue. Id. at 28, 39. In doing so, the Court explained that “the right to exclude others conferred in a patent can only be conferred upon one who has the common law right to use, make, and vend” the patented invention. Id. at 39; see also 8 Donald S. Chisum, Chisum on Patents § 21.03[1][n] (2006) (explaining that the Crown Die Court found it to be “essential that a patentee or assignee have some portion of the common law right to make, use, or sell when receiving the statutory right to exclude others”).

Crown Die may not clinch the argument for the defendants, but it does support the contention that the existence or absence of the right to practice the patent is significant in classifying the licensee’s status for standing purposes. Some decisions by the Federal Circuit reinforce, without rearticulating, Crown Die’s conclusion that the right to practice the patent is the *sine qua non* of patent standing.⁴ For example, the Federal Circuit has consistently characterized an exclusive licensee of fewer than all substantial rights (the second category in the

³ The Court did not use the term “licensee,” but used the term “assignee” to include what is now known as an exclusive licensee of fewer than all substantial rights. See Crown Die & Tool Co., 261 U.S. at 37.

⁴ It appears that only four Federal Circuit cases have found a licensee to be an exclusive licensee of fewer than all substantial rights, as E8 purports to be. In each of the cases, the licensee held the right to practice the patented invention. See AsymmetRx, Inc. v. Biocare Med., LLC, 582 F.3d 1314, 1316 (Fed. Cir. 2009); Int’l Gamco, Inc. v. Multimedia Games, Inc., 504 F.3d 1273, 1275 (Fed. Cir. 2007); Intellectual Prop. Dev., Inc., 248 F.3d at 1342; Abbott Labs., 47 F.3d at 1129.

taxonomy) as one holding a “license to practice the invention . . . accompanied by the patent owner’s promise that others shall be excluded from practicing it within the field of use wherein the licensee is given leave,” e.g., Textile Prods., Inc. v. Mead Corp., 134 F.3d 1481, 1484 (Fed. Cir. 1998) (quoting W. Elec. Co. v. Pacent Reproducer Corp., 42 F.2d 116, 118 (2d Cir. 1930)), and a bare license (the third category in the taxonomy) as one holding what “amount[s] to no more than a covenant by the patentee not to sue the licensee for making, using or selling the patented invention,” e.g., Ortho Pharm. Corp., 52 F.3d at 1031.

The defendants’ contention that the right to practice the patent is essential to patent standing is bolstered to some degree by the fact that E8 has not clearly disagreed. Rather, in its papers, E8 argued that the License Agreement granted it the right to manufacture licensed products. (See Pls.’ Mem. in Opp’n to Def.’s [Affymetrix] Mot. to Dismiss E8 Pharm. LLC for Lack of Standing 14.) At oral argument, E8 amended its argument and claimed that its right to practice the patent was evident (or inferable) from the License Agreement’s grant of the right to sublicense the right to practice—a right it could exercise to sublicense the right to practice to itself. (See Hr’g Tr. 25.)

There can be no dispute that the License Agreement contains no explicit grant of the right to manufacture licensed products or otherwise to practice the ’228 patent. Section 2.1 sets out the rights granted to E8 under the License Agreement and does not mention manufacturing or practicing the patent:

2.1 License Grants. Subject to the terms of this Agreement, M.I.T. hereby grants to COMPANY for the TERM the right to grant to any SUBLICENSEE(S) a royalty-bearing, prospective and/or retroactive license or covenant not to sue under the PATENT RIGHTS to develop, make, have made, use, sell, offer to sell, lease, or import LICENSED PRODUCTS in the FIELD in the TERRITORY and to develop or perform LICENSED PROCESSES in the FIELD in the TERRITORY during the TERM.

(Mem. in Supp. of Def.’s [Affymetrix] Mot. to Dismiss Pl. E8 Pharm. LLC for Lack of Standing Ex. K, § 2.1 [hereinafter License Agreement].)

In the absence of an explicit grant of the right to practice, E8 relies on another section of the License Agreement in claiming a right to practice:

2.4 U.S. Manufacturing. COMPANY agrees (a) to the extent that COMPANY is the sole entity licensed to manufacture LICENSED PRODUCTS (that is, COMPANY having not sublicensed others to do so); or (b) to the extent that COMPANY has granted an exclusive sublicense to a third part, then COMPANY or the third party (as the case may be) shall agree that any LICENSED PRODUCTS used or sold in the United States by that exclusive licensee/sublicensee of the PATENT RIGHTS will be manufactured substantially in the UNITED STATES. In the event that such U.S. manufacture proves to be non-viable economically, M.I.T., upon request by COMPANY, agrees to assist in seeking a waiver under 35 U.S.C. §§ 201-211 to allow the manufacture outside the United States for the U.S. market.

(Id. § 2.4.)

It is perhaps possible to read the “(a)” clause as implying that unless or until E8 grants a sublicense to manufacture licensed products to a third party, it holds the right to do so. If § 2.1 *had* included the right to manufacture, then the “(a)” clause of § 2.4 would be harmonious with such a grant and thus unremarkable. But § 2.1 does not explicitly grant the right to practice, and so E8 must argue that the “(a)” clause of § 2.4 requires giving effect to the supposition that MIT “must have meant” to grant E8 the right to practice even though it did not take care to say so. Apart from the general undesirability of employing a possible implication to overrule the expressed scope or limitations of a license grant (especially where as here, there is evidence of back-and-forth negotiation on the License Agreement’s terms), the suggested implication itself is rather weak. The thrust of § 2.4—and the reason for its inclusion—was not to describe or elaborate on the rights granted by the License Agreement, but to ensure that MIT complied with the Bayh-Dole Act’s United States manufacturing preference, 35 U.S.C. § 204. It appears § 2.4

was added at MIT's request rather late in the negotiation process to address the issue of compliance with the U.S. manufacturing preference, and its language closely mirrors the language of the regulation mandating a preference for United States manufacturing set forth in the Code of Federal Regulations. See 37 C.F.R. § 401.14(i). In sum, where the language of the expressed license grant is clear and unambiguous on its own terms, and where other language that could conceivably give rise to an implication of a broader grant is explainable otherwise, the proposed implication should be rejected.

E8's other argument is that it could sublicense the right to practice to itself and thus obtain that right, even if the License Agreement itself did not directly do so. In other words, while MIT may have limited the express license grant so as not to grant E8 the right to practice the patent, the License Agreement gave E8 the right to decide whether E8 should grant *itself* the right to practice, effectively overriding any expressed limitation in the language of the license grant.

E8's principals are inventors, after all, so give them credit for novelty. There is not the slightest reason to think, however, that such a construction of the License Agreement represents the parties' actual intent when they entered into the License Agreement, as opposed to an *ex post facto* rationale called into service when needed to meet the defendants' objections to E8's standing to sue. If MIT had actually intended to include the right to practice in the grant, it was a simple matter to express that intention in § 2.1. If MIT did not intend to include the right to practice (and therefore left it out of § 2.1), then construing the License Agreement to effectively grant the right in opposition to MIT's true intent would be plainly unreasonable.

I therefore conclude that the License Agreement does not grant E8 the right to practice the methods claimed in the '228 patent, and that the absence of the right to practice has

substantial significance, if it is not in itself conclusive, concerning the question of E8's putative standing as an exclusive licensee of fewer than all of the substantial rights.

B. Exclusionary Rights Under the '228 Patent

The limited exclusionary rights granted to E8 under the License Agreement shed further light on the standing question. The defendants argue that E8 is a bare licensee because MIT, like the patentee in Propat, retained control over key aspects of the patent rights. MIT's retained control, according to the defendants, renders E8 nothing more than "an agent for licensing and litigation" who lacks standing to sue. (Mem. in Supp. of Def.'s [Affymetrix] Mot. to Dismiss Pl. E8 Pharm. LLC for Lack of Standing 6.) In response, E8 submits that the License Agreement gives it exclusive control over all commercial exploitation of the '228 patent, including the right to control infringement litigation and to sublicense others to make, use, and sell the patented invention. It is necessary to examine each of these rights in turn.

E8 contends that it holds the unfettered right to determine who can receive a commercial sublicense and on what terms. (See License Agreement § 2.1.) This is not entirely true. If E8's right to grant sublicenses were truly unfettered, then E8 would also have discretion *not* to sublicense the patent to anyone. E8 does not have that negative discretion, however, because it is obligated to use "diligent efforts to identify potential SUBLICENSEES." (Id. § 3.1(a).) Requiring a licensee to use "diligent efforts" in its licensing efforts is "a provision that is more consistent with the status of an agent than a co-owner." See Propat Int'l Corp., 473 F.3d at 1194. Two additional limits to E8's right to determine who holds a sublicense are present in the License Agreement: MIT retains the right to demand termination of any sublicense if the sublicensee brings a patent challenge. (License Agreement § 12.4.) MIT must also give written permission before E8 can grant a sublicense for non-monetary consideration, although such

permission cannot be unreasonably withheld. (Id. § 1.7.) MIT thus retains important decision-making authority with respect to sublicenses, and E8's powers in this respect are subject to MIT's authority.

E8's power to set the terms of sublicense agreements is also limited. E8 must always include a provision setting forth MIT's right to terminate a sublicense, as described above, and must "incorporate terms and conditions into its sublicense agreements sufficient to enable [E8] and SUBLICENSEES to comply with this Agreement." (Id. § 2.3.) Importantly, E8 is obligated to name MIT as a third-party beneficiary under all sublicense agreements. (Id. § 3.1.)

Under the License Agreement, MIT also retains substantial oversight over E8's sublicensing efforts. E8 has a "continuing obligation during the TERM to enforce payments due pursuant to any sublicenses entered into under this Agreement." (Id.) MIT, as a third-party beneficiary, retains the right to step in and enforce payments if E8 fails to do so. (Id.) E8 is also required to "maintain, complete and accurate records" relating to all sublicenses, which MIT may inspect at any time. (Id. § 5.4.)

E8's contention that it holds an unfettered right to select commercial infringement targets and to control litigation is also not entirely true. (See id. § 7.2(a).) As with the right to sublicense, if E8's right to sue were unfettered, it would have the discretion to indulge infringement by *not* filing suit. E8 has no such negative discretion, but must use "diligent efforts to identify infringers." (Id. § 3.1(b).) This requirement obviously serves MIT's interests. Requiring a licensee to use "diligent efforts" in its enforcement efforts is "a provision that is more consistent with the status of an agent than a co-owner." Propat Int'l Corp., 473 F.3d at 1194. Although E8 need not obtain the consent of MIT before initiating litigation, as the licensee in Propat was required to do, it must nevertheless "consult with" and "consider the views of"

MIT “regarding the advisability of the proposed action and its effect on the public interest.” (License Agreement § 7.2(a)); see Propat Int’l Corp., 473 F.3d at 1194.

Moreover, E8 does not control all aspects of litigation. For instance, settlement is a critical aspect of litigation, and, like the bare licensee in Morrow, E8 must obtain MIT’s written consent before settling any infringement action. (License Agreement § 7.2(a)); see Morrow, 499 F.3d at 1341; see also Sicom Sys. Ltd. v. Agilent Techs., Inc., 427 F.3d 971, 979 (Fed. Cir. 2005) (inability to settle litigation disqualified licensee from being an exclusive licensee of all substantial rights). E8 also must share any litigation recovery with MIT—eighty percent to E8 and twenty percent to MIT. (License Agreement § 7.4.) Retention by the patentee of a “substantial share of proceeds is consistent with [the patentee’s] retaining ownership rights in the patent, while allocating to [the licensee] the duty to provide licensing and enforcement services.” Propat Int’l Corp., 473 F.3d at 1191.

E8 also lacks the right to assign its interest in the ’228 patent without MIT’s written consent, which cannot be unreasonably withheld. (License Agreement § 10.) “[A] restriction on a [licensee’s] right to assign is a substantial right reserved by the [patentee].” Intellectual Prop. Dev., Inc., 248 F.3d at 1345; see also Propat Int’l Corp., 472 F.3d at 1194 (“In this case, [the licensee] lacks important indicia of a true ownership interest in the patent, such as the right to transfer its interest.”); Sicom Sys. Ltd., 427 F.3d at 979 (“Just as the right to alienate personal property is an essential indicia of ownership, the right to further assign patent rights is implicit in any true assignment.”) (quoting Calgon Corp. v. Nalco Chem. Co., 726 F. Supp. 983, 988 (D. Del. 1989)).

Considering the substantial limitations on the rights granted to E8 and the substantial rights retained by MIT, along with the absence of a grant to E8 of the right to practice the ’228

patent, I conclude that E8 is a “bare licensee” lacking standing to sue. The License Agreement does not transfer sufficient exclusionary rights to, or ownership of, the ’228 patent to E8 for it to have suffered constitutional injury-in-fact from any alleged infringement by Affymetrix and Navigenics.

III. Conclusion

For the foregoing reasons, the defendants’ Motions to Dismiss Plaintiff E8 Pharmaceuticals LLC for Lack of Standing (dkt. nos. 34 and 134) are GRANTED. E8 is dismissed as a party plaintiff.

It is SO ORDERED.

/s/ George A. O’Toole, Jr.
United States District Judge